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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,527	10/10/2006	David Dakin Iorwerth Wright	07588.0082	7497

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EXAMINER

SOROUGH, ALI

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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11/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,527

Applicant(s)

WRIGHT ET AL

Examiner

Ali Soroush

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 24 and 25 recite the limitation "the at least one **other** physiologically acceptable gas" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claims 26 and 27 recite the limitation "the **other** physiologically acceptable gas" in lines 2-3 and 7 of claim 26, and lines 3-4 of claim 27. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

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3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osman et al. (International Application Published Under the PCT, Published 12/07/2000).

Applicant Claims

Applicant claims foam comprising a sclerosing agent and gas phase of 0.0001 to 0.8% nitrogen gas and at least one physiologically acceptable gas; a canister comprising the components of the foam and method of making the canister. Applicant further claims a method treating a patient with an injection of the foam.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Osman et al. teaches a microfoam comprising a physiologically acceptable gas that is dispersible in the blood and an aqueous sclerosant liquid wherein the sclerosant is aqueous polidocanol, the concentration of polidocanol being from 0.5 to 4% vol/vol in the liquid. The microfoam is characterized in that it has a density of 0.11 to 0.14 g/ml and a half-life of at least 2 minutes, more preferably 2.5 minutes, and most preferably 3 minutes. The more preferable physiologically acceptable blood dispersible gas comprises 70 to 80% vol/vol oxygen and 20 to 30% vol/vol carbon dioxide. Which may also comprise a minor portion of nitrogen gas. (See claims 49, 51, 55, and 58 and page 9, paragraph 1 and 3). Osman et al. further teaches a device for producing a microfoam where the chamber is pressurized at 0.01 to 0.9 bar over atmospheric pressure and

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comprises pressurized source of physiologically acceptable gas and upon an activation mechanism the gas being contacted with aqueous sclerosant liquid wherein the microfoam passes through a passage of cross-sectional dimension 0.1 to 30 μ m, preferably 5 to 25 μ m, and more preferably 10 to 20 μ m. (See claims 19, 20, 21 and 30 and page 11, paragraph 1). The canister is made by the method comprising pre-purging with 100% oxygen for 1 minute, filling the canister with 15 ml of sclerosing agent, and pressurizing with oxygen of 1.7 bar over atmospheric pressure and maintained at this pressure through the use of the canister. (See page 24, example 2). Osman et al. further teaches a method of treating a patient in need of sclerotherapy of a blood vessel comprising administering a microfoam to the blood vessel. The canister is such that it contains sufficient gas and solution to form up to 500ml of microfoam, more preferably 1 to 200 ml and most preferably 10 to 60 ml of microfoam to treat at least one varicose human saphenous vein. (See claim 65 and page 19, paragraph 5).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Osman et al. teaches a gas phase comprising carbon dioxide, oxygen, and minor amount of nitrogen gas. However, Osman et al. does not anticipate a gas phase comprising 0.0001 to 0.8% nitrogen gas but does make such a gas phase obvious.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have a gas phase comprising a mixture of carbon dioxide, oxygen,

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and 0.01 to 0.6% of nitrogen gas. One would have been motivated to use such a composition because Osman et al. teaches a gas phase comprising preferably 70 to 80% oxygen, 20 to 30% carbon dioxide, and a minor amount of nitrogen. It would therefore mean that the composition may comprise between 0 to 10% nitrogen which covers the instantly claimed concentration of 0.01 to 0.6% nitrogen. For the foregoing reasons the instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner
Art Unit: 1616


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